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SURGICAL INSTRUMENT SERVICE COMPANY, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

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| SURGICAL INSTRUMENT SERVICE COMPANY, INC.,<br>Plaintiff,<br>vs.<br>INTUITIVE SURGICAL, INC.,<br>Defendant. | Case No. _____<br>**1. SHERMAN ACT § 1 - TYING**<br>**2. SHERMAN ACT § 1 – EXCLUSIVE DEALING**<br>**3. SHERMAN ACT § 2 - MONOPOLY**<br>**4. SHERMAN ACT § 2 – ATTEMPTED MONOPOLY**<br>**5. VIOLATION OF LANHAM ACT**<br>**JURY TRIAL DEMANDED** |

## COMPLAINT

Plaintiff Surgical Instrument Service Company, Inc ("SIS") brings this Complaint against Defendant Intuitive Surgical, Inc. ("Intuitive") for antitrust violations of tying, exclusive dealing, monopolization, and attempted monopolization under the Sherman Act, and unfair competition under the Lanham Act.

## INTRODUCTION

1. SIS has 50 years of experience servicing surgical instruments and equipment ranging from simple devices such as forceps and scalpels to complex electromechanical devices such as flexible video endoscopes, powered orthopedic devices, and surgical video systems. SIS employs exhaustive inspection and repair procedures to ensure that previously used surgical instruments are only returned to the operating room in accordance with specifications. SIS's services save health care providers and patients millions of dollars a year, reducing the per-surgery cost of procedures without compromising instrument operation or patient safety. SIS is a trusted nationwide partner for hospitals, health care systems, and group purchasing organizations ("GPOs"), including in this District.

2. Since the late 1990's, defendant Intuitive has been the leading provider of robotic surgery systems for minimally invasive soft tissue surgeries. In contrast to operating directly on a patient, the surgeon using Intuitive's system remotely operates a multi-arm "da Vinci" surgical robot from a console that receives video of the surgical site and includes means for precisely controlling the movement and operation of surgical tools known as EndoWrists. EndoWrists include traditional surgical tools such as forceps and scalpels and are attached to the robotic arms based on the type of surgery to be performed. The robotic arms include motors that control cables within the EndoWrist in response to the surgeon's inputs, allowing precise multi-axis movement of the "wrist" of the surgical tool that is not possible in traditional surgeries.

3. Intuitive has monopoly power in the relevant markets of surgical robots for minimally invasive surgeries, the instruments used in such surgeries, and the servicing of those surgical robots, with a 99%+ market share. In the early 2000's, Intuitive's Form 10-K filings noted a use counter to limit the number of operations performed with EndoWrist instruments, and acknowledged its strategy to "sell the instrument for a fixed number of uses or hours and effectively price our EndoWrist instruments on a per-procedure or per-hour basis." As Intuitive has since gained and exercised monopoly power in the relevant markets, this strategy has become extremely profitable. Although revenue from the da Vinci robots initially exceeded revenue from



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instrument and accessory sales, by fiscal year 2013 Intuitive's revenues from instruments and accessories surpassed da Vinci robot revenue. By fiscal year 2019 instrument and accessories revenue exceeded $2.4 billion, or more than a $1 billion more than sales of da Vinci systems. Although Intuitive does not break out its gross profit for instruments alone, its gross profit on instruments and da Vinci systems is over 70%.

4. In connection with the purchase or lease of da Vinci Surgical products, Intuitive requires customers to enter into a Terms and Conditions Agreement ("Sales Agreement") and a Use, License and Service Agreement ("ULSA"). In connection with the agreements required to purchase or lease an Intuitive robotic surgical system, Intuitive demands that customers further agree to a limited license for the use of EndoWrist instruments. The limited license expires once an EndoWrist instrument is used up to its maximum number of uses as specified in the documentation accompanying the particular instrument. Intuitive's ULSA prohibits customers from engaging any unauthorized third party to repair, refurbish, or recondition EndoWrist instruments, whether before or after the limited use license has expired. Further, if a customer has or attempts to have an EndoWrist instrument repaired, refurbished or reconditioned, Intuitive has threatened to terminate the entire Use, License and Service Agreement with the customer immediately upon written notice, and any warranties applicable to the da Vinci robotic surgical system will become void. Intuitive has advised its customers that should Intuitive or its personnel determine, after having accepted a service call or a purchase order for a service call, such as after an Intuitive Field Service Engineer arrives at a customer's site for a service call, that the da Vinci robotic surgical system has been used with EndoWrist instruments refurbished or modified by any unauthorized third party, Intuitive will no longer provide any service for the customer's entire robotic system.

5. Plaintiff SIS has detailed procedures for servicing used EndoWrists to original specifications and returning them to service. These procedures include disassembly of the EndoWrist, inspection of all components, adjustment of components as necessary, confirming all movements, and setting a counter to Intuitive's original counter value. While these procedures are



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extensive and return the EndoWrist to original performance specifications, the cost to the hospital is a fraction of what Intuitive charges to buy a new EndoWrist. In 2019 and 2020, SIS entered into contracts and was in discussion for other contracts to provide EndoWrist repair services to numerous hospitals, health care systems, and GPOs. The cost savings were so substantial that one of the nation's largest health care systems awarded SIS's EndoWrist repair program a prestigious annual award for cost savings. Revenues for SIS, and savings to hospitals and patients, were anticipated to be in the tens if not hundreds of millions of dollars.

6. When Intuitive discovered that its customers were using SIS's services, it immediately leveraged its anti-competitive agreements and monopoly power to crush this threat to its supra-competitive EndoWrist profitability. Intuitive's agreements with hospitals include numerous restrictive terms that allow Intuitive to render the da Vinci robots effectively inoperable, and it threatened to exercise those terms against hospitals that used SIS's services. Intuitive also made misleading statements that use of refurbished EndoWrists would violate FDA requirements and intellectual property rights.

7. Despite the massive savings to hospitals and patients from SIS's EndoWrist program, SIS's customers and potential customers had no choice but to capitulate to Intuitive's threats. Because of Intuitive's monopoly power in minimally invasive surgical robots, the instruments for those robots, and the servicing of those robots, there are no realistic alternative suppliers in those relevant markets. Health care providers have made massive capital investments in da Vinci robots, surgeons are specifically trained to perform surgery with those robots, and a large number of patients choose da Vinci robotic surgeries despite a significantly higher out-of-pocket cost. To lose access to existing da Vinci robots would not only waste an expensive capital investment, but would effectively foreclose hospitals and surgeons from performing certain types of surgeries.

8. Intuitive's anti-competitive conduct cannot be justified by any purported safety or regulatory requirements. All components of the EndoWrists are medical-grade materials that are capable of many times more uses than permitted by Intuitive's unilaterally programmed counter.



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SIS's services ensure that the inspected or repaired EndoWrists meet all original specifications, and SIS sets the instrument counter to the original value provided by Intuitive. In sum, the only purpose of Intuitive's anti-competitive conduct is to maintain supra-competitive "per-procedure" EndoWrist pricing. By leveraging its monopoly power and anti-competitive agreements in this manner, Intuitive has violated the Sherman Act's prohibitions on monopoly, attempted monopoly, exclusive dealing and tying, and the Lanham Act's prohibition on unfair competition.

9. Intuitive is the dominant supplier of robotic surgical systems for minimally invasive soft tissue surgeries. Intuitive essentially has no competition in this market. Additionally, Intuitive is the dominant supplier of instruments used with minimally invasive soft tissue robots and the dominant supplier of servicing for the robots -- essentially having no competition in either of these markets as well.

10. Intuitive has used its monopoly power in the EndoWrist instrument replacement aftermarket, as well as in the servicing of surgical robots, to engage in a variety of anticompetitive practices. These exclusionary practices essentially prevent hospitals, health care systems, and GPO's from having access to competitors that offer to repair and refurbish EndoWrist instruments which have been previously used.

11. Intuitive wields its monopoly power in the market for robotic soft tissue surgery systems to coerce hospitals, health care systems, and GPO's to act in ways that have anticompetitive effects thus harming competition. Such coercion is backed up by Intuitive's threats to withhold technical support and servicing for the robotic surgery systems purchased by hospitals, health care systems, and GPO's and to deny those customers access to additional and/or replacement EndoWrist instruments.

## PARTIES

12. Plaintiff Surgical Instrument Service Company, Inc. is an Illinois corporation with a principal place of business at 151 N. Brandon Drive, Glendale Heights, Illinois.

13. Defendant Intuitive Surgical, Inc. is a Delaware corporation with a principal place of business at 1020 Kifer Road, Sunnyvale, California.



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## JURISDICTION AND VENUE

14. Jurisdiction - This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §§ 15, 22, and 1121. Defendant has been engaged in interstate commerce during all relevant times of the Complaint.

15. Jurisdiction - This Court has personal jurisdiction over Defendant due to its business activities in this District, including Defendant being headquartered in this District.

16. Venue is proper under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c). Intuitive is headquartered in this District and a substantial part of the events giving rise to all claims occurred in this District.

17. Intradistrict Assignment – Pursuant to Civil L.R. 3-2(c), the present action is an antitrust action that is assigned on a district-wide basis.

## GENERAL ALLEGATIONS

### I. SIS'S SURGICAL INSTRUMENT REPAIR BUSINESS

18. Founded in 1971, SIS has been a leader in surgical instrument and equipment service and repair for 50 years. During this time, SIS has safely and effectively serviced millions of surgical instruments for health care providers. SIS's best-in-class team, equipment, and processes are trusted by hundreds of hospitals throughout the country, including hospitals in this District. SIS does not merely inspect and repair surgical instruments, but also functions as an operational partner for its client hospitals, improving their operations and processes.

19. SIS services a wide variety of instruments, ranging from relatively simple mechanical devices such as traditional standard and laparoscopic instruments to complex instruments such as electrical and pneumatic saws and drills, a wide range of optical and video endoscopes, and surgical video equipment. Based on the FDA's Quality Systems Regulation (QSR) and current Good Manufacturing Practices (cGMP), SIS develops inspection and repair processes that ensure that any equipment returned to the hospital or surgical field will function properly.



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20. Based on this extensive experience with a wide range of surgical instruments, SIS is intimately familiar with the capabilities and lifespan of medical grade materials and components such as stainless steel, composites, and tungsten used in such devices. SIS technicians employ industry-leading procedures for inspection, alignment, sharpening, electrical insulation test, and additional necessary steps to return instruments to the field with confidence. Instruments that are regularly serviced by SIS are capable of dozens, hundreds, or thousands of uses over their lifetime, depending on the type of equipment and materials.

21. SIS's services, and those like it, are essential to the safe and cost-effective operation of hospitals throughout the country. SIS's preventative maintenance and inspection services ensure that instruments used in medical procedures and surgeries are safe. Its repair services substantially extend the life of surgical instruments, resulting in substantial savings for health care providers and patients.

## II. INTUITIVE'S DA VINCI SURGICAL ROBOTS AND ENDOWRISTS

22. For over 20 years, Intuitive has developed and sold the "da Vinci" line of minimally invasive surgical robot systems. A previous generation of da Vinci surgical robots that is currently being phased out is called the "Si," while the most recent "Xi" version was launched in 2014. Additional versions of these systems also exist under the X and SP monikers. Collectively, there are over 3,500 da Vinci robotic surgery systems employed by United States hospitals and surgery centers, and over 5,500 worldwide.

23. The da Vinci system generally includes a multi-arm surgical robot (left), surgeon's console (center), and a vision cart (right):



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24. A new da Vinci system, including the surgical robot vision cart, typically costs more than $2.0 million. Although Intuitive has begun leasing the da Vinci system to some customers, the vast majority (> 85%) of active da Vinci systems are purchased by hospitals as capital equipment.

25. The instruments used in the surgical procedure are attached to the arms of the surgical robot, and the surgical robot is positioned relative to the target surgical region of the patient. All of the 80+ instruments used with da Vinci robots are supplied by Intuitive under its EndoWrist brand. EndoWrist instruments are the only FDA-approved instruments for use with the da Vinci systems.

26. In a typical procedure, a number of small incisions are made to provide the EndoWrist surgical instruments access to the target surgical region. A camera provides high-definition 3D images to the surgeon at the surgeon's console and to other operating room personnel via a large screen of the vision cart. The surgeon directs the surgery by manipulating controllers on the console, which allow for precision control of the robot arms and EndoWrist instruments. This allows the surgeon to specify movements on a scale that is at least an order of magnitude less than the surgeon's actual hand movements at the console.

27. The surgical instruments located at the end of the EndoWrists, such as scalpels, clamps, forceps, scissors, and needle drivers, are substantially identical to similar instruments used



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in traditional surgeries. In fact, Intuitive reported to the FDA that EndoWrists and traditional surgical instruments "are essentially identical… in terms of shape, size, function, and tissue effect," "are substantially equivalent in intended use and/or method of operation," and "demonstrate substantial equivalence ... in terms of safety and effectiveness." The FDA agreed and "determined the [EndoWrist] device" is "substantially equivalent" to the traditional devices, and thus granted EndoWrist 510(k) certifications based on these predicate devices. EndoWrist devices are constructed from traditional medical grade materials, such as stainless steel, composites, and tungsten cables.

28. An example of the working end of an EndoWrist Force Bipolar instrument is depicted in the image below:

29. Many of the EndoWrist instruments have a wide degree of motion at the working tip of the instrument, capable of rotation in multiple planes, and providing an extra level of dexterity that is not available in traditional surgical instruments. The movement at the instrument tip is controlled by tungsten cables located within the EndoWrist. These tungsten cables are actuated by internal pulleys of the EndoWrist that mechanically interface with motors within the robot arms of the da Vinci system. The motors within the robot arms in turn cause the movement of the instrument tip commanded by the surgeon by changing the position of the pulleys and tungsten cables. For the vast majority of EndoWrist instruments, these mechanical components provide for all controls of the instrument tip within the EndoWrist.



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30. EndoWrists also include an internal memory chip. The internal chip does not control the movement of the EndoWrist instrument tip, but instead stores certain information about the particular EndoWrist, including a model number specific to the type of EndoWrist, a part ID specific to the particular EndoWrist, a chip ID for the chip itself, and a counter value for the particular EndoWrist.

31. The counter counts the number of times the EndoWrist is attached to a da Vinci robot arm, not an actual measure of usage such as usage time, number of movements, or actuation time. The chip also does not monitor the components of the EndoWrist for conditions that would be indicative of failure, such as the lack of response of the instrument tip to requested movement or a motor requiring excessive force to cause a desired movement of the tungsten cables.

32. The da Vinci robot system queries the memory chip prior to performing any operations with the particular EndoWrist instrument. After a certain number of uses, usually limited to ten, the EndoWrist instrument is rendered non-operational, based solely on the number of times it is attached to a da Vinci robot arm, without any regard to the actual underlying physical condition of the EndoWrist instrument. Without the services of providers such as SIS, the hospital has no choice but to buy a brand-new replacement EndoWrist instrument from Intuitive at full price.

## III. SIS'S ENDOWRIST REPAIR BUSINESS

33. Services of the type performed by SIS are permitted by the FDA. SIS has properly repaired millions of surgical devices and instruments over its 50 years in business as an independent services operator. After service by SIS, the surgical device or instrument is returned to the customer for its original intended use. Indications for use are not affected, and the surgical device or instrument is returned to its original safety and effectiveness.

34. SIS has created a program for the inspection and repair of EndoWrist instruments. The SIS repair procedures include an initial disassembly and inspection, checking the mechanical operation and integrity of all mechanical components, an electrical integrity check to confirm that electrical insulation, cleaning, sharpening or alignment of the instrument tip, and a series of tests



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to confirm that all the movements of the instrument tip are within original specifications. SIS also sets the counter to a value corresponding to the initial setting of a new EndoWrist instrument.

35. These procedures are similar to procedures that SIS has performed for decades on dozens of types of surgical instruments and medical devices of similar or greater complexity. The materials of the EndoWrist instruments are the same medical grade materials that typically last through hundreds of surgeries and autoclave cycles in other surgical instruments and in medical devices. Particularly after completion of SIS's rigorous set of procedures, the EndoWrist instruments are suitable for many more uses, and at least a number of uses equivalent to Intuitive's originally specified usage limit. In fact, independent testing has shown that EndoWrist instruments serviced by SIS are suitable for 50 or more uses. Nonetheless, SIS returns the counter value to the original value specified by Intuitive.

36. Throughout 2019 and 2020, SIS spoke with numerous hospitals, health care systems, and GPOs regarding its EndoWrist repair and refurbishment offering. These health care providers universally conveyed their frustration with Intuitive and its abusive business practices. In sum, Intuitive's aggressive and ever-changing tactics for extracting an exorbitant per-surgery fee for EndoWrists is financially damaging for hospitals and results in excessive costs for patients.

37. Accordingly, SIS entered into service contracts with a number of health care providers, including health care providers in this District and a nationwide GPO. Many of these health care providers were existing SIS customers, such that the ramp up for performing incremental services on EndoWrist instruments would be minimal. SIS was also in late-stage negotiations with numerous additional health care providers, including a number of large health care systems. These agreements and other likely customers would have been worth millions in annual revenue to SIS.

38. SIS has the experience, facilities, equipment, and personnel to perform inspection and repair for EndoWrist instruments nationwide. Just based on its initial contracts, SIS was prepared to service at least 1,500 EndoWrists a month. Based on potential agreements and SIS's



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existing experience and capacity, SIS could have easily ramped up these services to service thousands of additional EndoWrist instruments a month.

39. SIS charges approximately 30-45% less per EndoWrist than what a hospital would have to pay to buy a replacement EndoWrist from Intuitive.

40. While this is a substantial revenue source for SIS, these revenues pale in comparison to the cost savings to hospitals by using SIS to service EndoWrist instruments rather than throwing away and purchasing new EndoWrist instruments from Intuitive. The vast majority of Intuitive's $2.4 billion in annual instrument sales is for replacement EndoWrists, a large proportion or majority of which would not be needed under SIS's competitive offering. Indeed, even at its inception the cost savings for SIS's EndoWrist repair program were so substantial that one of the health care systems awarded the program its prestigious annual award for health care cost savings.

41. Unfortunately for health care providers and patients, Intuitive became aware of SIS's repair program and its relationships with certain health care providers. Intuitive immediately embarked on a scorched-earth pressure campaign to put SIS out of the EndoWrist repair business. And it worked. Faced with coercive threats from the monopoly provider of robotic surgical systems to effectively disable their expensive surgical robots, all of the health care providers backed out of SIS's EndoWrist repair program.

42. In just the last year, health care providers and patients have had to pay hundreds of millions of dollars for unnecessary replacement EndoWrist instruments based on Intuitive's anti-competitive conduct. Intuitive's monopoly power and its anti-competitive use of that power are detailed in the following sections.

## IV. INTUITIVE'S MONOPOLY POWER IN THE RELEVANT MARKETS

43. There are three relevant markets for purposes of this action: (1) the worldwide and domestic market for surgical robots used in minimally invasive soft tissue surgery; (2) the worldwide and domestic market for repair and maintenance for surgical robots used in minimally



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invasive soft tissue surgery; and (3) the worldwide and domestic market for replacement or repair of instruments for use with surgical robots used in minimally invasive soft tissue surgery.

44. Intuitive has monopoly power in (1) the worldwide and domestic market for surgical robots used in minimally invasive soft tissue surgery, (2) the worldwide and domestic market for repair and maintenance for surgical robots used in minimally invasive soft tissue surgery, and (3) the worldwide and domestic market for replacement or repair of instruments for use with surgical robots used in minimally invasive soft tissue surgery, such that Intuitive is able to exclude virtually all competition and charge supra-competitive prices in those markets. With respect to the "repair" aspect of (3), Intuitive has leveraged its monopoly power in robots and instruments, and service of those robots, to prevent any repair services from existing and competing within the EndoWrist instrument aftermarket.

*(1) The Market for Surgical Robots Used in Minimally Invasive Soft Tissue Surgery*

45. Intuitive's da Vinci surgical robots are primarily used in minimally invasive soft tissue surgery. Initially cleared by the FDA in 1999, the da Vinci robot was the only FDA-cleared surgical robot until 2015. As of 2015, Intuitive had over 3,500 active da Vinci surgical robots at hospitals worldwide.

46. **The market for minimally invasive soft tissue surgery using surgical robots is distinct from minimally invasive procedures performed without surgical robots**, primarily due to the advantages that robotic surgery provides and the public perception which comes with those advantages.

47. In a traditional laparoscopic surgery performed without a da Vinci robot, a number of trocars are placed through the skin in the target area, and function as placeholders for the surgical instruments or other devices subsequently used to perform the surgery. The surgical instruments and a 2-dimensional camera are then manipulated through a number of small incisions in the target area of the patient, while being manipulated or held by the surgeon(s), nurse(s), surgical assistant(s), and physical supports. More complex laparoscopic surgeries typically require more trocars.



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48. Like laparoscopic surgery, minimally invasive robotic surgeries are advantageous over traditional open surgeries, in that the surgery is performed through a number of small incisions rather than a large incision of open surgery, resulting in decreased infection rates, faster recovery, and better patient outcomes. But da Vinci robot surgeries also have substantial advantages over laparoscopic surgeries. Rather than physically holding surgical instruments or attaching them to physical supports, the da Vinci robotic surgeries have precision robot arms that accurately hold instrument working tips in position without causing physical strain. The surgeon is seated at an ergonomic console viewing a 3D image of the surgical region. The surgeon is not limited by his or her own physical dexterity in manipulating surgical instruments, but can instead make large scale movements at the console that are translated to precision microscopic movements of surgical instruments. Most of the EndoWrist surgical instruments have a precision-controlled full range of motion about multiple axes at the working end of the instrument, as compared to the limited range of motion and limited precision available with just the human wrist and fingers. Based on the advantages of robotic surgery, some procedures such as prostatectomies are frequently performed by surgeons that exclusively operate using surgical robots.

49. Intuitive, many hospitals, many doctors, and many patients believe that minimally invasive robotic surgeries are superior to laparoscopic surgeries. For example, Intuitive advertises that da Vinci surgeries provide "improved outcomes" and "fewer complications" than non-robotic surgery options. A number of clinical studies support the claim that minimally invasive robotic surgeries are more effective and safer than laparoscopic surgery. There is a perception among many doctors and patients that minimally invasive robotic surgeries are safer and more effective than traditional laparoscopic surgeries. Perceptions are such that Intuitive states that "100% of the top-ranked U.S. hospitals for cancer, urology, gynecology and gastroenterology diseases all use da Vinci surgical systems" and "100% of top-ranked U.S. hospitals own at least one da Vinci System."

50. There is hardly any cross-elasticity of demand between minimally invasive robotic surgical procedures and laparoscopic procedures. The estimated per-surgery cost of the robot,



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instruments, equipment, and service for robotic surgery is over three times as much as the comparable costs for laparoscopic surgery, at over $3,500 versus under $1000. Most insurance plans pay the same amount for minimally invasive robotic surgery and laparoscopic surgery, such that patients pay much more out of pocket for minimally invasive robotic surgery and hospitals have lower (and sometimes negative) margins on minimally invasive robotic surgery. Despite the substantial financial incentives for both patients and hospitals to prefer laparoscopic surgery, the estimated procedure volume for robotic surgery increased from 136,000 in 2008 to 877,000 in 2017 for a compounded annual growth rate of 23%. *Id.* In sum, an increase in the cost of a minimally invasive surgical robot, instruments, and service does not lead doctors or patients to choose laparoscopic or traditional surgery equipment instead, nor would a change in the cost of traditional or laparoscopic equipment affect the market for minimally invasive surgical robots, instruments, and service.

51. Indeed, many surgeons specialize in minimally invasive robotic surgeries to the exclusion of laparoscopic surgery. According to Intuitive's annual report for fiscal year 2019, surgeons have performed approximately 1.2 million surgeries with da Vinci robots over the last 20 years. Professional and trade associations such as the Society of Robotic Surgery and the Clinical Robotic Surgery Association are focused on robotic surgery.

52. Hospitals that do not have robots such as the da Vinci robots for minimally invasive robotic surgeries are unable to recruit an entire cohort of surgeons and lose out on a large volume of potential surgeries. Because many surgeons perform almost exclusively robotic surgeries, many doctors will go to extraordinary measures to gain access to da Vinci surgical robots, including performing surgery from multiple hospitals and scheduling surgery in the middle of the evening to gain access to a da Vinci robot.

53. **The market for surgical robots used in minimally invasive soft tissue surgery is distinct from the market(s) for other robotic surgeries**. Intuitive is the owner of a large portfolio of patents that have blocked competitors from entering into the surgical robot market for





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minimally invasive soft tissue surgery. Intuitive also invests heavily to ensure that doctors and medical students are trained to use, and ultimately become dependent on, the da Vinci system.

54. Most non-Intuitive surgical robots target entirely different types of surgeries than multi-incision minimally invasive soft tissue surgery. Stryker's Mako surgical robots, Smith+Nephew's Cori system, and Zimmer Biomet's Rosa platform are used for orthopedic surgeries such as knee and joint replacements. Siemen's Corindus surgical robots are used for coronary and peripheral vascular procedures. Medrobotics received FDA clearance for its Flex robot for use in natural orifice surgeries. Titan Medical surgical robots is seeking to release a surgical robot limited to single-port surgery. None of these robots compete with Intuitive's da Vinci robots, or in the minimally invasive surgical robot market.

55. The few companies that purport to sell robots for minimally invasive surgery have virtually no sales. Medical device company Asensus (formerly known as TransEnterix) received FDA clearance for a minimally invasive surgical robot, the Senhance Surgical Robotic System, in October 2017. However, this robot does not perform numerous surgeries that can be performed with a da Vinci robot, such as cardiothoracic surgery, urologic surgery, and a number of other procedures. In 2019, Asensus shipped 4 Senhance surgical robots worldwide, none of which were in the United States. In contrast, in 2019, Intuitive shipped 1,119 da Vinci surgical robots worldwide, including 728 in the United States. Other medical device companies, such as Medtronic, have plans to enter the minimally invasive robot market, but they have no market share as their products are in the development stage.

56. Intuitive's long-time market dominance provides numerous advantages that prevent competition in the market for minimally invasive surgical robots. No other company that sells or has plans to sell a surgical robot has a comparable patent portfolio to the dozens of patents that cover Intuitive's da Vinci robots. Nor do they have the installed base of thousands of robots at hospitals in the United States and worldwide, or the thousands of surgeons who have undergone extensive training specific to da Vinci robots and since performed hundreds of surgeries with da Vinci robots.



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57. As confirmed by Intuitive's market dominance, it is extremely difficult for competitors to enter the robotic surgery market. FDA clearance takes five to ten years and costs tens or hundreds of millions of dollars from concept to FDA approval, and may require premarket approval, which is much more difficult than 510(k) premarket clearance. Similar regulatory hurdles exist in other jurisdictions, such as the European Union.

58. **Accordingly, Intuitive has a 99% market share in the worldwide and domestic markets for surgical robots used in minimally invasive soft tissue surgery.** Indeed, Intuitive's dominance in the robotic surgery market is so great that even if surgical robots used for entirely different procedures such as orthopedic surgery are considered, recent estimates of Intuitive's overall share of the robotic surgery market range for 77% - 80%.

59. The installed base of da Vinci robots and the prevalence of da Vinci-trained surgeons precludes new products from gaining market share in the market for minimally invasive surgical robots. Intuitive has an installed base of over 5,500 da Vinci robots worldwide. Switching to a different surgical robot system would be costly for hospitals, requiring them to purchase expensive new robots. A switch would meet substantial resistance from doctors, who would need to abandon the da Vinci surgical methods they have been performing for years (for some, their entire careers), and re-learn how to perform surgeries with different surgical robots. At a 99% market share, including "100% of top-ranked hospitals," the resistance to change does not only affect the few hospitals which do not have da Vinci robots. It affects an enormous portion of the available consumer base.

60. Intuitive's market power allows it to obtain supra-competitive margins on its product sales. Although Intuitive does not distinguish between robot and instrument sales for gross margin, its 2019 form 10-K demonstrates over 70% gross margin for robots and instruments. Intuitive's net margin is over 30% based on $1.38 billion in net income on $4.48 billion of total revenue. These margins are significantly higher than margins for typical medical device companies, surgical robotic companies, or other companies that make complex medical equipment.



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61. In sum, Intuitive has monopoly power in the worldwide and domestic markets for the sale of surgical robots used in minimally invasive soft tissue surgery. Intuitive is able to and does exclude competition and maintain prices for da Vinci robot systems at supra-competitive levels.

*(2) The Market for Service of Robots Used in Minimally Invasive Soft Tissue Surgery*

62. Intuitive extends its market power in the worldwide and domestic markets for the sale of surgical robots used in minimally invasive soft tissue surgery to the market for repair and support services for their robots.

63. Once a customer makes the purchase of a DaVinci robot, the only practical service option is service and repair services offered by Intuitive.

64. Hospitals are dependent on these robot maintenance services for the continued operation of their essential da Vinci robots. The services include "provid[ing] and install[ing]Software upgrades," "replac[ing] defective malfunctioning System parts," and "replac[ing] and install[ing] Software, Hardware, and mechanical parts for safety." Each of these services can only be obtained from Intuitive. And if these services are not provided—e.g., if a malfunctioning part is not replaced or the Software is not up to date—the da Vinci system will display a "NEEDS SERVICE" warning message on the display panel. Doctors will not perform a surgery with a machine indicating that it "NEEDS SERVICE." Nor will patients allow themselves to be operated upon by a machine that "NEEDS SERVICE." Accordingly, when service is needed, the da Vinci robot is effectively rendered useless until service is provided by Intuitive. Hospitals cannot afford to have useless da Vinci robots. Da Vinci robots are large capital investments, and ongoing da Vinci surgeries are necessary to recoup that investment. Functional da Vinci machines are also necessary to maintain the goodwill of the doctors and patients who have scheduled robotic surgeries.

65. Intuitive leverages its market power in the worldwide and domestic markets for the sale of surgical robots used in minimally invasive soft tissue surgery, and the market for repair



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services for their robots, to pressure its customers to use supra-competitively priced replacement EndoWrist parts.

*(3) The Market for Replacement and Repair of Instruments for Use with Surgical Robots Used in Minimally Invasive Soft Tissue Surgery*

66. Although Intuitive maintains a significant patent portfolio in its surgical robots, any blocking patents for its EndoWrist instruments are long expired. Intuitive maintains a "Patent Notice" web page for its products. Virtually all of the patents covering core structure and operations for the "EndoWrist" and "Accessories" are expired. The few patents that remain in force are related to specific instrument implementations and could not block a third party from selling competing instruments for use with Intuitive da Vinci robots. Intuitive instead uses technical and contractual means to ensure that only Intuitive-supplied EndoWrists are used with da Vinci robots.

67. One way Intuitive maintains EndoWrist exclusivity is by programing the da Vinci robots to require that any EndoWrist attached has an Intuitive serial number in order to operate. This tactic prevents third parties from manufacturing da Vinci compatible EndoWrists. Intuitive's standard sales contract for da Vinci robots also prohibits customers from using the robot with any surgical instruments not made by or approved by Intuitive. Customers are left with access to only one source for EndoWrists—Intuitive.

68. Even if a third party were to successfully create an alternative EndoWrist, the alternative would have to get FDA approval before entering the market. This, in combination with the other mentioned factors, prevents EndoWrist alternatives from becoming available.

69. Instruments used for other types of surgical robots, such as orthopedic surgery robots, are not compatible with minimally invasive soft tissue surgery robots. Because they are used in different types of surgeries and do not operate in as small of spaces, they employ different tools and do not include multi-axis end-tool movement control in the same manner as EndoWrists.



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70. Accordingly, Intuitive has a 99% market share for instruments used with minimally invasive soft tissue surgery robots, because 100% of instruments used with Intuitive da Vinci robots are sold by Intuitive.

71. Intuitive's market power in instruments used with minimally invasive soft tissue surgery robots is demonstrated by its lucrative revenue and profits in its EndoWrist business. By fiscal year 2019, instrument and accessories (primarily EndoWrists) revenue exceeded $2.4 billion, or more than a $1 billion more than sales of da Vinci systems. Although Intuitive does not break out its gross profit for instruments alone, its gross profit on instruments and da Vinci systems is over 70%. Indeed, the bulk of Intuitive's revenue and profit growth over the last decade has come from its sales of EndoWrist instruments, not robotic systems, as demonstrated from data from Intuitive's 10-Ks from 2001 to 2019, below:

| Year | 2001 | 2002 | 2004 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|---|---|---|---|---|---|---|---|
| Instruments ($M) | $5.0 | $10.1 | $18.8 | $37.5 | $67.8 | $111.7 | $191.6 | $293.0 |
| Systems ($M) | $44.2 | $56.3 | $61.8 | $78.8 | $124.6 | $205.9 | $324.4 | $455.3 |

| Year | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 |
|---|---|---|---|---|---|---|---|---|
| Instruments ($M) | $389.4 | $528.8 | $701.1 | $903.3 | $1,033 | $1,070 | $1,198 | $1,396 |
| Systems ($M) | $490.5 | $660.3 | $777.8 | $932.9 | $834.9 | $632.5 | $721.9 | $800.0 |

| Year | 2017 | 2018 | 2019 |
|---|---|---|---|
| Instruments ($M) | $1,637 | $1,962 | $2,408 |
| Systems ($M) | $928.4 | $1,127 | $1,346 |

72. Indeed, while Intuitive's sales of robots were stagnant from 2012 – 2017, Intuitive's EndoWrist sales increased by over $730 million dollars during that time period. As is described in the following paragraphs, the bulk of Intuitive's EndoWrist windfall revenue, and thus the bulk of its corporate revenue and profitability, is based on its anti-competitive conduct that requires



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hospitals to purchase replacement EndoWrists rather than repairing EndoWrists that are capable of many more uses at a significantly reduced price.

73. The vast majority of Intuitive's EndoWrist revenue and profit, and thus its overall revenue and profit, comes from *replacement* EndoWrists. The da Vinci robots are typically in service for years, if not a decade or more, and EndoWrists provide a recurring revenue stream. In the words of Intuitive's Form 10-Ks from the early 2000's, EndoWrist instruments include a counter that allows it to "sell the instrument for a fixed number of uses or hours and effectively price our EndoWrist instruments on a per-procedure or per-hour basis."

74. Specifically, the EndoWrist chip includes a counter that counts the number of times the EndoWrist is attached to a da Vinci robot arm. This is not an actual measure of usage such as usage time, number of movements, or actuation time. The chip does not monitor the components of the EndoWrist for conditions that would be indicative of failure, such as the lack of response of the instrument tip to requested movement or a motor requiring excessive force to cause a desired movement of the tungsten cables. The counter is set to a variety of values for different instruments such as 10, 12, 15, 18, 30, and 100. For virtually all EndoWrists instruments, the counter is set to the lower part of that range, and the vast majority of EndoWrist instruments have their counter set at 10 attachments.

75. Intuitive has unilaterally changed counter values for types of EndoWrist instruments and its pricing for those instruments. Intuitive has also unilaterally changed the instructions for use (IFU) for EndoWrist instruments to force early replacement, even if the counter value has not expired. For example, Intuitive issued an IFU for EndoWrist instruments setting a maximum number of autoclave cycles. Because of the way that da Vinci surgeries are prepped and performed, EndoWrist instruments often have to undergo an autoclave cycle even if not actually attached to a robot during surgery. The specified limit on autoclave cycles is extremely low compared to comparable devices made of similar medical grade materials. These unilateral changes substantially increase the per-surgery cost of EndoWrist instruments to hospitals, and Intuitive's supra-competitive EndoWrist profits, without prior notice to hospitals. When hospitals



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make the substantial capital and contractual commitment to purchase a da Vinci robot, they are unaware of these additional costs and lack information to predict Intuitive's unilateral changes.

76. Intuitive does not provide hospitals any option for repair of the EndoWrist instrument after the counter has expired. Instead, once the counter has expired the hospital must purchase a new EndoWrist at a cost ranging from $2,250 - $3,750, without regard to whether the EndoWrist instrument was actually used in surgery or the extent of such use.

77. At least SIS has attempted to enter the market for repair of instruments for use with surgical robots used in minimally invasive soft tissue surgery, and specifically, for repair of EndoWrists. On information and belief, other companies similar to SIS have attempted to enter this market.

78. As described previously herein, SIS employs meticulous procedures to inspect, and as necessary, repair EndoWrist instruments. Once the EndoWrist is returned to original specifications, SIS sets the counter to the same value originally programmed by Intuitive. Based on its 50 years of expertise in surgical equipment repair and the demonstrated safety and efficacy of its EndoWrist repair process, SIS entered into contracts and was in negotiations for contracts with hospitals, health care providers, and GPOs representing thousands of EndoWrists a year and tens of millions in revenue, just in the first year.

79. An EndoWrist serviced by SIS would cost only 55-70% of the cost of buying a replacement EndoWrist from Intuitive, and would be equally safe for the same number of subsequent uses.

80. Although SIS's business was poised to grow substantially year-over-year, SIS's expected sales of tens of millions of dollars in 2020 would still amount to less than 1% market share for replacement and repair of EndoWrists. SIS had obtained and was in the process of repairing EndoWrists from some of these initial customers, when Intuitive embarked on a scorched-earth campaign to put SIS out of the EndoWrist repair business. SIS repaired Endo Wrists that were successfully used in surgeries without any problems or incidents.



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81. In view of Intuitive's 99% market share for minimally invasive soft tissue surgery robots, 100% market share for the servicing and support of those robots, and the 100% market share of instruments used with Intuitive da Vinci robots, Intuitive has leveraged its monopoly power in all these markets and engaged in other anti-competitive acts to prevent repair of instruments for use with surgical robots used in minimally invasive soft tissue surgery. Intuitive's wrongful acts are described in the following section.

## V. INTUITIVE'S MONOPOLIST TACTICS AND ANTI-COMPETITIVE ACTS

82. Intuitive has engaged in an anticompetitive course of conduct consisting of several primary anticompetitive practices. Intuitive has harmed competition through and by these practices.

83. One of Intuitive's anticompetitive practices involves requiring its customers for the da Vinci robotic surgical system to agree to numerous restrictive terms that allow Intuitive to subsequently disable and effectively render the da Vinci robots inoperable at some later time (for example, by refusing to service the robots).

84. A second anticompetitive practice involves unilaterally modifying the terms for EndoWrists once a hospital has invested in a da Vinci robot, such as unilateral changes in pricing, use limits, and restrictive instructions for use.

85. A third anticompetitive practice employed by Intuitive involves refusing to provide hospitals, health care systems, and GPOs with an option to have their previously used EndoWrist instruments repaired after the internal counter has expired.

86. A fourth anticompetitive practice used by Intuitive involves requiring customers who purchase its da Vinci robotic systems to agree that they will not permit the repair or refurbishment of any EndoWrist instruments by a third party. If a customer violates this prohibition, Intuitive has threatened to void the warranties on the da Vinci robotic system, completely terminate the agreement with that customer, refuse to provide further service and support for the robotic system, and even render the surgical robot inoperable.



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87. An effect of Intuitive's anticompetitive conduct is to generate and sustain unreasonably high, supra-competitive prices for aftermarket EndoWrist instruments.

88. Intuitive's anticompetitive conduct effectively forecloses customers who have purchased da Vinci robotic surgery systems from having access to competitive sources of aftermarket EndoWrist instruments in violation of the Sherman Act Sections 1 and 2.

89. Through Intuitive's coercive practices directed at da Vinci customers, it foreclosed rivals from supplying customers with aftermarket EndoWrist instruments through repair and refurbishment services. In so doing, Intuitive maintains its monopoly power in the EndoWrist instrument aftermarket which it has used to sustain unreasonably high replacement rates and supra-competitive prices.

90. Intuitive's practices have the practical effect of preventing a buyer of a da Vinci robotic system from using the products and services of a potential competitor in the EndoWrist instrument aftermarket. Intuitive's practices have prevented SIS's entry as a rival into the EndoWrist instrument aftermarket.

91. On information and belief, Intuitive became aware that SIS was providing owners of da Vinci robots with repaired EndoWrist instruments in late 2019.

92. Between late 2019 to early 2020, Intuitive sent letters to and had in-person conversations with SIS's customers or potential customers, knowing that they were under contract or in contractual negotiations for repaired EndoWrists. As a result of the threats and misleading statements in those letters and conversations, all of SIS's EndoWrists customers backed out of their contracts or did not sign contracts under negotiation, effectively eviscerating SIS's EndoWrist repair business.

93. In letters to SIS customers and potential customers, Intuitive claimed that repairs might lead to "degraded performance," including "unintuitive motion," "insufficient grip force," "dull or damaged scissor blades," and "worn/damaged cables." To the contrary, under SIS procedures all of these aspects of EndoWrist performance, and numerous others, are inspected in detail and repaired as necessary to meet Intuitive's original equipment specifications.



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94. Intuitive also alleged that "third party manufacturers or refurbishers may use non-validated or incompatible cleaning agents and/or disinfection/sterilization processes" or "may damage the instrument's internal mechanisms that interface with the robotic system and allow Intuitive to monitor the device." To the contrary, with years of experience working with millions of diverse devices that require sterilization procedures, SIS processes do not employ "incompatible cleaning agents and/or disinfection/sterilization processes." Nor would SIS return a device to the customer that was damaged or could not interface properly with Intuitive's robotic system.

95. In sum, if Intuitive had only alleged that SIS's services might potentially cause these issues, SIS's customers and potential customers would have had no worry whatsoever doing EndoWrist business with SIS. SIS has a sterling reputation of repairing surgical devices such as EndoWrists, and robust processes specific to the EndoWrists.

96. Intuitive instead asserted numerous threats and misleading statements by letter and in private conversations to prevent SIS from performing its repair services, and to maintain its monopoly profits in EndoWrists.

97. A first set of Intuitive's misleading statements made by letter relates to FDA clearances. Couched in terms of "might prevent such products from performing" such that FDA and other regulations "may not apply," Intuitive states without any basis that "the hospital has no way to know whether the refurbished instrument meets the rigorous specifications" of Intuitive and the FDA. Intuitive also states that "any modification to allow for use of a da Vinci product beyond its useful life exceeds the scope of the original clearance by expanding the FDA cleared indications for use" in violation in 21 U.S.C. § 351.

98. The components of the EndoWrists are medical grade parts with a useful life of dozens if not hundreds of uses. They will operate within specification, particularly when properly inspected and repaired as is performed by SIS. Intuitive's allegation appears to be that use of EndoWrists beyond the counter limit is a violation of Intuitive's FDA clearances. Based on FDA clearances that have been identified for EndoWrists to date, this assertion is incorrect. At most,



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Intuitive merely mentions in its FDA applications that its devices have usage limits. Available 510(k) summaries are silent on usage limits, and have no prohibitions whatsoever on repair.

99. A second misleading statement made by letter relates to unspecified "intellectual property rights in the da Vinci systems and its instruments" that "Intuitive believes it has[.]" SIS merely repairs EndoWrists, which according to Intuitive's own Patent Notice webpage do not have any relevant patent rights that would cover SIS's services. Nor are there any other intellectual property rights that SIS's services would call into question.

100. Intuitive's letters also inform SIS customers of certain "terms of [the customer's agreements with Intuitive] that you might wish to consider." According to Intuitive, such terms include prohibitions on "repair, refurbishment, or reconditioning" and another asserts that the hospital's "license [for an EndoWrist] expires once an Instrument or Accessory is used up to its maximum number of uses[.]" Another term referenced by Intuitive states that the hospital will not "permit any third party to, modify, disassemble, [or] reverse engineer . . . the System or Instrument or Accessories." Failure to comply with the latter term results in termination of the hospital's "Agreement immediately upon written notice, and any warranties applicable to the system will become void."

101. Notably, the Agreement that Intuitive is referring to and the remedies it is threatening are for the "System," *i.e.*, the surgical robot. These terms constitute attempts by Intuitive to constrain its customers with illegal exclusive dealing agreements, and constitute illegal tying of EndoWrists and EndoWrist related services to the original purchase of the da Vinci robot. These provisions are particularly egregious in view of Intuitive's market power in the market for minimally invasive surgical robots. The effectiveness of its exclusive dealing and tying requirements are proven by Intuitive's market power in the market for replacement instruments for minimally invasive surgical robots, and its ability to completely foreclose the market for repair of such instruments.

102. Intuitive's letters make its threats explicit—if the hospital uses repaired instruments, Intuitive will render its surgical robot inoperable. Not only will Intuitive seek



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damages or indemnity from its customer, but if Intuitive discovers "Systems being used with instruments by an unauthorized third party, Intuitive may no longer accept your service calls for such Systems." Because Intuitive also refuses to allow any competition in the market for service of its robots, and refuses to make error codes and other critical information available to third parties, failure to provide such service will render a robot that originally cost well over a million dollars inoperable. Many hospitals have multiple such robots that would thus be rendered inoperable.

103. Intuitive's letter continues, stating that "[s]hould Intuitive or its personnel determine, after having accepted a service call or a purchase order for a service call, such as after an Intuitive Field Service Engineer arrives at your site for a service call, that the System has been used with instruments refurbished or modified by an unauthorized third party, Intuitive may not provide service for such a System." Again, the threat is explicit—if the hospital uses refurbished instruments, Intuitive will render its surgical robot inoperable.

104. In private conversations, Intuitive representatives have made this threat even more explicit. In response to one hospital's use of third-party repair services, an Intuitive representative stated that Intuitive would turn the surgical robot into a "paperweight."

105. These threats provide further evidence of Intuitive improperly leveraging its monopoly power in the relevant markets to maintain its lucrative EndoWrist sales and margins, and to prevent the development of a repair market at all costs.

106. Intuitive has also engaged in other anticompetitive conduct to protect and expand its EndoWrist monopoly. As described herein, Intuitive unilaterally changes counter values and pricing for EndoWrist instruments, and has unilaterally changed IFUs to require replacement of EndoWrist instruments after an unreasonably low number of autoclave cycles.

107. For its most recent Xi generation of da Vinci robots and EndoWrist instruments, Intuitive has made an inordinate investment in encryption and other countermeasures of the internal EndoWrist chip. There is no technical or safety justification for these excessive efforts, except to prevent third parties such as SIS from accessing the counter. Specifically, it would not



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be possible to operate an EndoWrist instrument with a da Vinci robot if other values of the EndoWrist chip such as the EndoWrist serial number were modified. Intuitive's sole purpose is to prevent competition in repair services and to unjustifiably protect its supra-competitive EndoWrist profits. Intuitive's anti-competitive conduct operates to the detriment of patients, hospitals, and SIS, by using unjustified technical measures to prevent an EndoWrist repair market from existing for the Xi EndoWrists.

108. In order to protect its EndoWrist monopoly pricing, Intuitive has taken steps to force customers to switch from da Vinci robots (typically "S" and "Si" robots) for which EndoWrist repair is possible to Xi da Vinci robots for which EndoWrist repair is not currently possible. For example, Intuitive has announced that as of 2023 it intends to stop selling S and Si EndoWrist instruments, and to discontinue providing service and technical support for da Vinci S and Si robots. By withdrawing service and technical support, Intuitive is effectively rendering these robots inoperable.

109. Intuitive has offered favorable terms and pricing to induce customers to move from S and Si da Vinci robots to Xi robots, knowing that it can recoup lost revenue many times over by preventing repair of Xi EndoWrist instruments.

110. In sum, Intuitive has gone to extraordinary efforts to leverage its monopoly power in robots for use in minimally invasive soft tissue surgery, the repair and support of those robotic systems, and its monopoly power in instruments for use with such robots to foreclose aftermarket repair of those instruments by any competitors. This costs hospitals and patients at least 30-45% per instrument (which savings would increase over time) or hundreds of millions of dollars a year in a $2.4 billion market, without any safety or technical justification.

**COUNT I – TYING**

111. SIS incorporates all of the above paragraphs as though fully set forth herein.

112. Intuitive has dominant economic power in the worldwide and domestic markets for surgical robots for minimally invasive soft tissue surgery, for servicing, support and repair of those



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robots, and with respect to instruments for use with such robots. Intuitive has used this economic power to coerce its customers into buying EndoWrists from Intuitive rather than allowing the option of repairing EndoWrists through experienced service organizations such as SIS. Intuitive has conditioned the sale and servicing of its da Vinci surgical robots on customers buying replacement EndoWrists from Intuitive instead of permitting the use of EndoWrists that customers previously purchased but later had repaired, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. This tying arrangement has anticompetitive effects in the worldwide and domestic markets for repair and replacement of instruments for surgical robots for minimally invasive soft tissue surgery, which involves a substantial amount of interstate commerce.

113. As a direct and proximate result of the foregoing conduct, Intuitive has forced customers to purchase unnecessary EndoWrists at supra-competitive prices, and SIS has been injured, including through lost profits, lost customers, and damage to its reputation and goodwill. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

**COUNT II – EXCLUSIVE DEALING**

114. SIS incorporates all of the above paragraphs as though fully set forth herein.

115. Intuitive has taken measures and entered into agreements with its customers that require the customers to replace their EndoWrist instruments on an exclusive basis with new Intuitive EndoWrists, thus foreclosing competition in the worldwide and domestic markets for repair and replacement of instruments for surgical robots for minimally invasive soft tissue surgery, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. This exclusive dealing has anticompetitive effects in the worldwide and domestic markets for repair and replacement of these instruments, which involves a substantial amount of interstate commerce.



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116. As a direct and proximate result of the foregoing conduct, Intuitive has forced customers to purchase unnecessary EndoWrists at supra-competitive prices, and SIS has been injured, including through lost profits, lost customers, and damage to its reputation and goodwill. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

**COUNT III – MONOPOLIZATION**

117. SIS incorporates all of the above paragraphs as though fully set forth herein.

118. Intuitive has willfully obtained and maintains monopoly power in the worldwide and domestic markets for repair and replacement of instruments for surgical robots for minimally invasive soft tissue surgery in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Intuitive maintains at least a 99% market share by excluding competitors. Intuitive's exclusionary tactics include tying EndoWrist replacements and repairs to sales and servicing of da Vinci surgical robots, prohibiting customers from having their EndoWrists repaired, sending cease and desist letters when customers attempt to have EndoWrists repaired, and employing countermeasures to the Xi instrument usage counter to prevent any modification of the usage counter.

119. As a direct and proximate result of the foregoing conduct, Intuitive has forced customers to purchase unnecessary EndoWrists at supra-competitive prices, and SIS has been injured in its business and property, including through lost profits, lost customers, and damage to its reputation and goodwill. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

**COUNT IV – ATTEMPTED MONOPOLIZATION**

120. SIS incorporates all of the above paragraphs as though fully set forth herein.



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121. Intuitive has acted with the clear intent to obtain monopoly power in the worldwide and domestic markets for the repair and replacement of instruments for surgical robots for minimally invasive soft tissue surgery in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Intuitive has engaged in anticompetitive conduct including tying EndoWrist replacements and repairs to sales and servicing of da Vinci surgical robots, prohibiting customers from having their EndoWrists repaired, sending cease and desist letters when customers attempt to have EndoWrists repaired, and employing countermeasures to the Xi instrument usage counter to prevent modification of the usage counter. Intuitive has at least a 99% market share and has a high probability of successfully monopolizing the market.

70. As a direct and proximate result of the foregoing conduct, Intuitive has forced customers to purchase unnecessary EndoWrists at supra-competitive prices, and SIS has been injured in its business and property, including through lost profits, lost customers, and damage to its reputation and goodwill. These injuries are antitrust injuries, because they flow from that which makes Intuitive's conduct unlawful under the Sherman Act.

**COUNT V- UNFAIR TRADE PRACTICES – VIOLATION OF LANHAM ACT**

122. SIS incorporates all of the above paragraphs as though fully set forth herein.

123. Intuitive, in connection with the sale of its EndoWrist instruments, asserted false or misleading descriptions of facts or representations in its correspondence with its and SIS's customers and such misrepresentations were likely to cause consumer confusion or inaccurately describe the nature, characteristics, or qualities of its and SIS's commercial activities in violation of Section 43 of the Lanham Act, 15 U.S.C. § 1125.

124. Intuitive has at least misrepresented that SIS's services are contrary to FDA approvals of the EndoWrist products and are in violation of intellectual property rights. Intuitive



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sent such correspondence to multiple SIS customers and potential customers. Intuitive made such statements knowingly, willfully, and/or recklessly that such statements were misleading. These misleading statements affected the purchasing decisions of such customers.

125. Intuitive's misrepresentations were made to SIS's customers, and upon information and belief, a significant number of Intuitive customers that have, or had, Intuitive Si robots.

126. SIS has been injured in its business and property, including through lost profits, lost customers, and damage to its reputation and goodwill. These injuries flow from that which makes Intuitive's conduct unlawful under the Lanham Act. SIS is entitled to all relief available for such misleading statements, including but not limited to injunctive relief, disgorgement of Intuitive's ill-gotten profits, recovery of SIS's damages, attorneys' fees, the costs of this action, and treble damages under the Lanham Act, 15 U.S.C. § 1117(a).

**Prayer for Relief**

SIS respectfully requests that the Court enter judgment in its favor and against Intuitive as follows:

(a) For damages in an amount to be determined at trial and trebled pursuant to 15 U.S.C. §§ 15(a) and 1117(a);

(b) For injunctive relief pursuant to 15 U.S.C. §§ 26 and 1116;

(c) For costs and attorney's fees incurred in this action pursuant to 15 U.S.C. §§ 15(a) and 1117(a);

(d) For such other and further relief as the Court deems just and proper.

**Jury Demand**

Plaintiff demands trial by jury for all claims.



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Dated: May 10, 2021

**HALEY GUILIANO LLP**

By: */s/ Joshua Van Hoven*

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